

Date: January 12, 2023.

Time: 12:00 P.M. TO 3:00 P.M.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, barnardm@extra.nidk.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 23, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–28358 Filed 12–28–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIDDK.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, including consideration of personnel

qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDDK.

Date: October 12–13, 2023.

Open: October 12, 2023, 10:00 a.m. to 10:20 a.m.

Agenda: Introductions and Overview.

Place: National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Closed: October 12, 2023, 10:20 a.m. to 5:40 p.m.

Agenda: To review and evaluate to review and evaluate to review and evaluate to review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Closed: October 13, 2023, 10:00 a.m. to 3:10 p.m.

Agenda: To review and evaluate to review and evaluate to review and evaluate to review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael W. Krause, Ph.D., Scientific Director, NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Health, Building 5, Room B104, Bethesda, MD 20892–1818, (301) 402–4633, mwkrause@helix.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 23, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–28373 Filed 12–28–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered Cell Therapies for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and

Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Affini-T Therapeutics, Inc. (“Affini-T”), headquartered in Watertown, MA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before January 13, 2023 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)–276–5484; Email: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 63/185,805 filed May 7, 2021, entitled “T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53” [HHS Reference No. E–101–2021–0–US–01]; and

2. PCT Application No. PCT/US2022/028066 filed May 6, 2022, entitled “T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53” [HHS Reference No. E–101–2021–0–PCT–02].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

“Development, manufacture and commercialization of T or Natural Killer cell therapy products genetically engineered to express the P53 R175H-reactive T cell receptor claimed in the Licensed Patent Rights for the treatment of cancer in humans.”

E–101–2021 patent family is primarily directed to isolated TCRs reactive to certain mutated forms of tumor protein 53 (TP53 or P53), within the context of several human leukocyte antigens. P53 is the archetypal tumor suppressor gene and the most frequently mutated gene in cancer. Contemporary estimates suggest that >50% of all tumors carry mutations in P53. Because of its prevalence in cancer and its restricted expression to precancerous and cancerous cells, this antigen may be targeted on mutant P53-expressing tumors with minimal normal tissue toxicity.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 22, 2022.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2022-28357 Filed 12-28-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Pathway to Independence (K99/R00) Special Emphasis Panel.

Date: March 6, 2023

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Latarsha J. Carithers, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, (301) 594-4859, latarsha.carithers@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 23, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-28377 Filed 12-28-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, SAMHSA will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including leveraging automated data collection techniques or other forms of information technology.

Proposed Project: Community Mental Health Services Block Grant and Substance Abuse Prevention and Treatment Block Grant FY 2024-2025 Plan and Report Guidance and Instructions (OMB No. 0930-0168)

SAMHSA is requesting approval from the Office of Management and Budget (OMB) for an extension of the 2024-2025 Community Mental Health Services Block Grant (MHBG) and Substance Abuse Prevention and Treatment Block Grant (SABG) Application Plan and Report Guidance and Instructions.

Currently, the SABG and the MHBG differ on a number of their practices (e.g., data collection at individual or aggregate levels) and statutory authorities (e.g., method of calculating MOE, stakeholder input requirements for planning, set asides for specific populations or programs, etc.). Historically, the Centers within SAMHSA that administer these block grants have had different approaches to application requirements and reporting. To compound this variation, states have different structures for accepting, planning, and accounting for the block grants and the prevention set aside within the SABG. As a result, how these dollars are spent and what is known about the services and clients that receive these funds varies by block grant and by state.

SAMHSA has conveyed that block grant funds must be directed toward four purposes: (1) to fund priority treatment and support services for individuals without insurance or who cycle in and out of health insurance coverage; (2) to fund those priority treatment and support services not covered by Medicaid, Medicare, or private insurance offered through the exchanges and that demonstrate success in improving outcomes and/or supporting recovery; (3) to fund universal, selective and targeted prevention activities and services; and (4) to collect performance and outcome data to determine the ongoing effectiveness of behavioral health prevention, treatment and recovery support services and to plan the implementation of new services on a nationwide basis. SAMHSA's five priorities (Preventing Overdose; Enhancing Access to Suicide Prevention and Crisis Care; Promoting Resilience and Emotional Health for Children, Youth and Families; Integrating Behavioral and Physical Health Care; and Strengthening the Behavioral Health Workforce) are highlighted and states are encouraged to incorporate